2 EQUIPMENT, REAGENTS AND SUPPLIES

The purpose of the procedures in this section is to ensure that the parameters of the testing process are routinely monitored in the manner necessary to maintain the success and reliability of the testing procedures. To ensure that the supervisor in each laboratory is aware of the quality control and quality assurance issues that affect his/her section on a monthly basis the supervisor and/or the individual assigned the task of overseeing the quality assurance/control, will conduct a documented review of the equipment calibration/maintenance logs (e.g., temperature logs) to ensure that the documentation is completed correctly. In addition, upon the completion of the quality control testing of critical reagents the supervisor or designee will review, initial and date the quality control documentation prior to the critical reagent being used to conduct casework or Data Bank analyses.

Controls utilized during each phase of the testing procedure are designed to signal potential problems in the analysis. If acceptable results are obtained on these controls, it is reasonable to assume that the results for other samples analyzed using the same equipment, reagents, and supplies will be accurate and acceptable. If the controls indicate a problem with the analysis, it may be possible to determine the source of the problem and correct for it. Depending on the nature of the problem, re-analysis of the samples may be required.

Where the samples are irreplaceable and/or limited in amount (as in most casework), it is highly desirable to minimize the need for repeat analysis due to failure of equipment, materials or reagents. To that end, quality control (QC) procedures should focus as much as possible on preventing problems before they occur rather than on dealing with them after they happen.

2.1 Instruments and Equipment

2.1.1 Inventory

An inventory of instruments and equipment will be maintained in accordance with Administrative Operating Procedure (AOP) 7, Inventory of Equipment. An inventory of the Instruments and equipment that is covered by AOP 7 will be recorded using the Division of Forensic Science "Adjustment of Inventory (Fixed Asset)"form, which is located in the Division's forms directory in the Outlook/Public Folder/All Public Folders/Forms/DFS Forms.

2.1.2 Operating Manuals

Warranty information and operating manuals will be filed in the laboratory and will be readily available to all operators of instruments and equipment.

2.1.3 Calibration/Maintenance/Repair Records

Anytime an instrument or piece of equipment requires calibration, service or maintenance, that fact will be documented on an "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form. Additionally, instruments/equipment on routine service contracts will have routine service calls documented. These forms will be maintained in a ring binder or properly labeled file.

2.1.4 Calibration and Maintenance Schedules

Routine maintenance and/or calibration will be performed on each instrument/piece of equipment considered essential for PCR-based typing based upon the following schedule:

NOTE: Unless otherwise specified, refer to the manufacturer's instrument/equipment operating manual for the maintenance and calibration procedure of each piece of equipment. If an instrument/equipment is out of calibration with the manufacturer's or the Forensic Biology Section's specifications, the instrument/equipment will immediately be taken off line for repair and the maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form". If an instrument/equipment is out of calibration and cannot be repaired it will be taken off line and the attempted repair will be documented on the "Equipment Calibration/Maintenance/Repair Form". Subsequently, the instrument/equipment in accordance with AOP 7, will be removed from the section's inventory and will be documented on the "Adjustment of Inventory (Fixed Asset)" form. Unless otherwise noted, the following procedures will be performed by laboratory personnel.

- **ANALYTICAL BALANCES:**

Biennially - Serviced and calibrated by outside vendor. Record the service call on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

Quarterly - Perform calibration check using calibrated weights and record results. Because there are many different analytical balances used throughout the Forensic Biology Section the weights used to verify the calibration of the analytical balance should include at least 3 data points covering the range for which the analytical balance is used.

PASS/FAIL RANGES FOR EACH DATA POINT (WEIGHT)

0.1 g	+/- 0.005
1.0 g	+/- 0.01
10 g	+/- 0.1
50 g	+/- 0.1
100 g	+/- 0.5
400 g	+/- 1.0
500 g	+/- 1.0
1.0 kg	+/- 1.0

If the analytical balance is outside of the acceptable range re-calibrate the balance a second time prior to making a service call.

As Needed - Serviced and calibrated by outside vendor.

If the balance is taken off line for repair/maintenance, prior to being put back in service, the quarterly calibration check will be conducted.

- **AUTOCLAVE:**

  Annually - Check the rubber gasket around the door to ensure that it has not deteriorated or the unit is not leaking and document the verification on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A. As necessary, depending on the unit, replace the rubber gasket in-house or have it replaced by an outside vendor. Document the service call on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

  Monthly - Verify and record operating temperature and pressure using a biological indicator. (Refer to Appendix B for the procedure.)

  Each Use - Check the temperature and pressure gauges to ensure the autoclave is working properly. Monitor autoclave tape indicator.

  As Needed - Clean. Have authorized vendor service.

  If the autoclave is taken off line for repair/maintenance, prior to being put back in service, the monthly biological indicator test will be conducted.

- **BIOMEK® 2000 WORKSTATION:**

  Each Day of Use - Check and record the temperature of the water bath. Ensure the water level is at the correct height. If the temperature is greater than $\pm$ 2.0^{0}C from the specified temperature of 75^{0}C the thermostat will be adjusted to obtain the correct temperature. The water bath temperature will be re-read and documented. If the correct temperature cannot be achieved the water bath will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

  Weekly –Perform precision test. Refer to the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Procedure Manual Section IV, BioMek® 2000 Automation Workstation Procedures Manual , Appendix C for instruction on performing this test.

  Monthly – Base module, left side module, and the shaker/thermal exchange alignment test. Refer to the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Procedure Manual Section IV, BioMek® 2000 Automation Workstation Procedures Manual, Appendix C for instruction on performing these test.

  As Needed – Inspect the tubing that leads from the water bath to the thermal exchange unit and replace if cracked or worn. Document the in-house maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

If the BioMek® Workstation is taken off line for repair/maintenance, prior to being put back in service, the weekly and monthly calibration tests will be conducted.

- **CENTRIFUGES:**

  Annually - Using a photoelectric tachometer check and record the speed of the rotor. (Refer to Appendix C for the procedure.)

  If a centrifuge is only used to pulse spin samples it is not necessary to quality control check the centrifuge rotor speed using a tachometer.

  Each Use - Wipe out the inside of the centrifuge with 70% ethanol or isopropanol.

  As Needed - Clean and replace brushes. Have authorized vendor service and calibrate. Document the authorized vendor's service or the in-house maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

  If a centrifuge is taken off line for repair/maintenance, prior to being put back in service, the annual tachometer check will be conducted.

- **DNA CONCENTRATOR/EVAPORATOR:**

  Monthly - Check oil level and replace when dirty. Document the in-house maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

  Each Use - Wipe out the inside of the DNA concentrator/evaporator with 70% ethanol or isopropanol.

  As Needed - Clean solvent collection trap. Document the in-house maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **ELECTROPHORESIS TANKS**

  Each Use - Rinse with distilled water (including the platinum wire), and air dry.

  As Needed - Wash with mild soap, replace electrodes, banana clips, gaskets or o-rings. Document replacements on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **FLUORESCENT IMAGING ANALYSIS SYSTEM (FMBIO II AND FMBIO III PLUS):**

  Annually - Have authorized vendor evaluate and perform necessary maintenance and repair. Document the service call on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

  As Needed - Use a Kimwipe dampen with water to wipe the inside of the unit to remove dried acrylamide.

- **FREEZERS (- 20^{0}C):**

  Weekly - Check and record temperatures each Monday. If the temperature checks cannot be performed on Monday due to a holiday, they will be made on the first regularly scheduled work day following the holiday. If the temperature is greater than -10^{0}C the thermostat will be adjusted to lower the temperature. Afterward the temperature will be monitored and recorded on a daily basis for the following week to ensure that the temperature does not increase. If the temperature continues to rise above -10^{0}C the freezer will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form.

- **HEAT BLOCKS:**

  Weekly (and prior to putting into service)- Check and record temperature. If the temperature on the thermometer while in the hole of the block designed to hold the thermometer is greater than $\pm$ 2.0^{0}C from the specified temperature (e.g., 37^{0}C, 56^{0}C, or 95^{0}C) the thermostat will be adjusted to obtain the correct temperature. The heat block temperature will be re-read and documented. If the correct temperature cannot be achieved the heat block will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

  Each Use - Check temperature.

- **HOODS:**

  BIOLOGICAL SAFETY CABINETS (EVIDENCE HANDLING AND PCR SETUP)

  Refer to the Commonwealth of Virginia Department of Criminal Justice Services Division of Forensic Science Safety Manual – Appendix A: Chemical Hygiene Plan, Section 7.1.2 Exhaust Hoods and Snorkels.

  Each Use - Wipe down the inside of the hood with 10% bleach (or a solution that will degrade DNA) followed by cleaning with isopropyl alcohol and/or ethanol before each use. If the hood is equipped with an alarm and the alarm sounds when the hood

is in use, and will not reset, the hood will be taken off line until it can be repaired. An authorized vendor will be contacted to repair the hood. The maintenance/repair will be documented.

FUME HOODS

Refer to the Commonwealth of Virginia Department of Criminal Justice Services Division of Forensic Science Safety Manual:

- Appendix A: Chemical Hygiene Plan, Sections 7.1.1 Ventilation and 7.1.2 Exhaust Hoods and Snorkels

- Appendix B: Exposure Control Plan, Section 4.2.2 Exhaust Hoods and Biological Safety Cabinets

BENCH TOP AIRCLEAN WORKSTATIONS (PCR SETUP)

Annually - Have authorized vendor evaluate and perform necessary maintenance and repair. Record the service call on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

Quarterly - Change pre-filter. Record the maintenance on the "Equipment Calibration/Maintenance/Repair Form". It is desirable to have one of the quarterly filter changes coincide with the annual vendor evaluation.

Biennially - Check HEPA filter and change as necessary. Record the maintenance on the "Equipment Calibration/Maintenance/Repair Form". It is desirable to have one of the biennial filter changes coincide with the annual vendor evaluation.

Each Use - Wipe down inside of the hood with 10% bleach. Do not use isopropanol or ethanol in the workstation.

- **INCUBATORS:**

If the incubator is used only to dry glassware it is not necessary to verify the temperature as specified below.

Weekly - Check and record temperatures. If the temperature is greater than $\pm$ 2.0^{0}C from the specified temperature (e.g., 37^{0}C, 56^{0}C, or 95^{0}C) the thermostat will be adjusted to obtain the correct temperature. The incubator temperature will be re-read and documented. If the correct temperature cannot be achieved the incubator will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form.

Each Use - Check temperature.

- **NIST TRACEABLE THERMOMETER:**

  Purchase a new NIST traceable thermometer when the unit needs to be re-calibrated. Maintain documentation of the calibration of the NIST traceable thermometer.

  NOTE: NIST traceable thermometers are good for 2 years from their original date of calibration.

- **ORBITAL SHAKERS:**

  As Needed - Lubricate and change brushes. Document the maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **OVENS:**

  If the oven is used only to dry glassware it is not necessary to verify the temperature as specified below.

  Weekly - Check and record temperatures. If the temperature is greater than $\pm$ 2.0^{0}C from the specified temperature (e.g., 37^{0}C, 56^{0}C, or 95^{0}C) the thermostat will be adjusted to obtain the correct temperature. The oven temperature will be re-read and documented. If the correct temperature cannot be achieved the oven will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form.

  Each Use - Check temperature.

- **pH METER:**

  Each Day of Use - Check and record the calibration at two set points.

  As Needed - Check solution in probe and replace. Document the maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **PIPETTES:**

  Annually - Have an authorized vendor evaluate and perform necessary maintenance and repair. Record this service on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form and retain the calibration certificate generated by the vendor. This serves to demonstrate that the pipette has passed QC prior to being put back into service.

  As Needed- Clean inside/outside with isopropyl alcohol. (Refer to Appendix D for the

procedure.) Once the pipette has been reassembled conduct a quick calibration check using the graduated Rainin Pipette Tips discussed in Appendix D. If a pipette appears to be out of calibration, it will be sent to an authorized vendor for repair. Record this service on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form and retain the calibration certificate generated by the vendor.

As Needed - If a pipette appears to be out of calibration between normally scheduled performance/calibration checks, the pipette will be sent to an authorized vendor for repair. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form and retain the calibration certificate generated by the vendor.

MULTI-CHANNEL PIPETTES:

Annually (if used to for precision measurements) - Have an authorized vendor evaluate and perform necessary maintenance and repair. Record this service on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form and retain the calibration certificate generated by the vendor.

- **QIAGEN® BIOROBOT™ 9604**

Refer to the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Manual Section V, Forensic Biology Section Qiagen® BioRobot™ 9604 Procedures Manual, Appendix D, Calibration and Maintenance of the BioRobot™ 9604, for the procedure on performing these calibration and maintenance checks.

- **REFRIGERATORS (4^0C):**

Weekly - Check and record temperatures each Monday. If the temperature checks cannot be performed on Monday due to a holiday, they will be made on the first regularly scheduled work day following the holiday. The temperature should fall between 1-6^0C. If not, the thermostat will be adjusted accordingly to bring the temperature into this range. Afterward the temperature will be monitored and recorded on a daily basis for the following week to ensure that the temperature does not fall outside of this range. If the temperature continues to fall outside of this range the refrigerator will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form.

- **THERMAL CYCLER VERIFICATION UNIT:**

  Annually - Send the thermal cycler verification unit to an authorized vendor for calibration. Record the calibration/maintenance check on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **THERMAL CYCLER:**

  9600 Thermal Cycler: Quarterly - Perform and record the results of the heater, chiller, temperature uniformity, and temperature calibration verification diagnostic tests. If any of the tests fail, contact an authorized vendor. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form. Record the results of the verification test on the appropriate worksheet provided in Appendix I. (Refer to Appendix F for the procedure.)

  9700 Thermal Cycler: Quarterly - Perform and record the results of the temperature calibration, temperature non-uniformity and the system performance diagnostic tests. If any of the tests fail, contact an authorized vendor. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form found in Appendix A or comparable log form. Record the results of the verification test on the appropriate worksheet provided in Appendix J. (Refer to Appendix G for the procedure.)

  If a thermal cycler is taken off line for repair/maintenance, prior to being put back in service, the quarterly calibration tests will be conducted.

- **THERMOMETERS:**

  Annually - Check calibration of each thermometer in use against a NIST or NIST traceable thermometer. (Refer to Appendix E for procedure.) If the temperature is greater than $\pm$ 1.0^{0}C from the temperature of intended use (e.g., 37^{0}C, 56^{0}C, or 95^{0}C) the thermometer will not be used to monitor temperatures at that range. If the thermometer is greater than $\pm$ 1.0^{0}C for more than one temperature range the thermometer will be removed from service and documented.

  Check the calibration of all new thermometers against a NIST or NIST traceable thermometer prior to putting into service.

  As Needed - Clean with mild detergent.

- **TYPE 1 WATER SYSTEM:**

  Each Use - Check set point to ensure the OHMs are within the manufacturer's specified range. If the unit is outside of the range of the manufacturer's specifications, change filters/cartridges and/or have an authorized vendor clean and check unit.

Record the replacement/maintenance check on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

As Needed - Change filters/cartridges, desanitize, and/or have an authorized vendor clean and check unit. Record the replacement/maintenance check on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **UV TRANSILLUMINATOR**

Each Use - Wash with water and/or 70% Isopropyl alcohol. Periodically wash with mild soap and wipe down with water.

- **VACUUM PUMPS**:

This pertains to stand alone vacuum pumps only and not building wide systems.

As Needed - Add oil, clean and flush vacuum lines. Record the maintenance on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

- **WATER BATH:**

Weekly - Check for cleanliness

Each Day of Use - Check and record temperature. Ensure the water level is at the correct height. If the temperature is greater than $\pm$ 2.0^{0}C from the specified temperature (i.e., 37^{0}C or 75^{0}C for the water baths that are attached to the BioMek 2000 Automation Workstations) the thermostat will be adjusted to obtain the correct temperature. The water bath temperature will be re-read and documented. If the correct temperature cannot be achieved the water bath will be removed from service until it can be repaired. The maintenance/repair will be documented on the "Equipment Calibration/Maintenance/Repair Form" found in Appendix A or comparable log form.

As Needed - Clean and replace water.

2.2 Reagents, Chemicals, and Supplies

2.2.1 Sources of Reagents, Chemicals, and Supplies

A listing of commercial sources for all reagents, chemicals, and supplies is found in the Commonwealth of Virginia Division of Forensic Science Forensic Biology Section Procedure Manual, Section III, Fluorescent Detection PCR-Based STR DNA Protocol PowerPlex® 16 BIO System.

2.2.2 Reagents, Chemicals and Supply Inventory

Upon receipt of all reagents, chemicals and supplies, the packing slip will be checked for agreement with the items received. A copy of each packing slip initialed and dated by the receiver will be maintained as a permanent record. If the packing slip does not contain the lot number of the reagent or chemical, the individual inventorying the item will add the lot number to the packing slip. The date of receipt, date opened, date of verification (if appropriate) and initials of the person performing the verification and/or opening the reagent/standard will be marked on all incoming reagent/chemical/supply.

NOTE: Reagents and supplies which have passed the expiration date will not be used on casework or Data Bank samples. However, these reagents/supplies may be used on non-critical samples (i.e., training samples, research gels, etc.) and will be appropriately labeled as such.

2.2.3 Material Safety Data Sheets (MSDS)

The MSDS received from the manufacturer for each chemical used in the laboratory can be found in the designated MSDS book. These data sheets will be kept current and readily available to all laboratory personnel.

2.2.4 Laboratory Prepared Reagents and Solutions

2.2.4.1 All laboratory prepared reagents and solutions will be made with great care and using good laboratory practices.

2.2.4.2 A log will be maintained for each laboratory prepared reagent/solution, including dilutions of laboratory concentrates. Each reagent/solution prepared will have the following information recorded in the log book:

- chemicals used
- commercial sources of chemicals
- lot numbers of chemicals
- date prepared
- initials of individual preparing reagent/solution
- expiration date
- other pertinent data, such as pH
- lot number

The lot number assigned to laboratory prepared reagents/solutions will consist of the date prepared (two digit numerical representation of month, day and year) and the initials of the preparer.

Example: Lot number 100803TM represents a reagent/solution prepared on October 8, 2004 by Teresa Mathis.

2.2.4.3 Labeling Requirements

All laboratory prepared reagents/solutions will be clearly labeled.
Labels will include reagent/solution identity, concentration, date of preparation, initials of preparer, and, as appropriate, storage requirements and expiration date as specified in the DNA procedure manual.

2.2.5 Storage and Disposal

All chemicals must be stored, used, and disposed of in a manner conforming to established safety requirements.

2.2.6 Critical reagents and supplies

All critical reagents and supplies must be quality control tested for accurate, reliable performance prior to being used in the Forensic Biology Section on casework or Data Bank samples. Refer to Section 3, Quality Control Of Critical Reagents and Supplies. The results of all quality control tests will be maintained in a ring binder or properly labeled file.

♦**END**